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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,456		Vered Hornik	2254-031	2896
28765	7590	07/01/2003		
WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502			EXAMINER	
			BORIN, MICHAEL L	
ART UNIT		PAPER NUMBER		
1631		20		
DATE MAILED: 07/01/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/644,456

Applicant(s)

Hornik et al.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Apr 11, 2003

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1-11 and 29-39 is/are pending in the application.

4a) Of the above, claim(s) 7-11, 31, 33-36, and 39 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-6, 29, 32, and 37 is/are rejected.

7)  Claim(s) 30 and 38 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3

6)  Other:

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## DETAILED ACTION

### *Status of Claims*

Claims 1-11,29-39 are pending.

Examiner acknowledges response to communication mailed 03/05/2003.

In regard to claims belonging to the elected Group, Examiner agrees that the claims 1-6,29,30,32,37,38 should be examined at this time. In regard to claims 29,37 suggested by applicant to be included into consideration, the claims are addressed only to the extent they read on the elected subject matter (i.e., compounds of formula 3 that are included in claim 29 when R3 in formula of claim 29 is absent); note the issues of new matter in relation to claims 29,37 addressed below.

In regard to election of species, Examiner acknowledges applicant's comment that LysC3 and AsnN2 are not modified amino acids but rather C3 and N2 denote the atoms at which the bridging group is connected. Insofar as the elected compounds have been found to be neither anticipated nor rendered obvious by the prior art, the Examiner has extended his search to include all species encompassed by the elected claims.

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***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29,37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 29,37 introduce new matter as they present a new generic formula (which blends together formulas 3 and 4) which encompass genus not described in the application as filed.

***Claim Rejections - 35 USC § 102 and 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-6,32 are rejected under 35 U.S.C. 102(b) as anticipated by Freidinger et al. (US 4,235,886).

Generic claims 1-6,32 are drawn to broadly defined backbone cyclized peptide. As such the claims read on any cyclic peptide satisfying the minimum structural requirements recited in the claims. The reference of Freidinger is used as an exemplary reference.

Freidinger et al teach cyclic hexapeptide somatostatin analogs and pharmaceutical compositions thereof. See col. 11, and claims 1-12. The referenced compounds satisfy structural requirements of instant claims 1-4. In regard to claims 5,6, the claim limitation "derived" is read as any derivation of peptide structure (e.g., substitution) which may result, for example, in the referenced peptides. In regard to the functional limitation, even if a reference does not teach the functional limitation of the peptide, such a limitation would be inherent in the peptide since it meets the structural limitations of the claim. A reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. In re Oelrich, 212, USPQ 323 (CCPA 1981). Where the claimed and prior art products are identical or substantially identical in structure or composition, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

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"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 15USPQ2d 1655, 1658 (Fed. Cir., 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

***Information Disclosure Statement***

The information disclosure statement filed 2/16/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

***Drawings***

There are no original drawings filed in this application. Please submit original drawings for draftsman's review.

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***Conclusion.***

Claims 30,38 are novel and unobvious over the prior art of record or any combination thereof. The prior art of record does not teach or suggest cyclic peptides as claimed.

Claims 30,38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 25, 2003

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

mlb

